K081070

Interlace Medical, Inc.
Operative Hysteroscopy System
510K Summary of Safety and Effectiveness JUL 23 2008
April 11, 2008

1. Sponsor Name

Interlace Medical Inc.
139 Newbury St
Framingham, MA 01701
Telephone: 508.875.1343

2. Device Name

Proprietary Name: Interlace Medical Operative Hysteroscopy System
Common/Usual Name: Hysteroscope and accessories

3. Identification of Predicate or Legally Marketed Device

The Interlace Medical Operative Hysteroscopy System is substantially equivalent to the Smith and Nephew Hysteroscope and Accessories cleared under K013870

4. Device Description

The Interlace Medical Operative Hysteroscopy System is intended for use in visualizing the uterine cavity and performing operative hysteroscopy procedures. The Operative Hysteroscopy System includes an obturator, a sheath and a hysteroscope. The obturator is used to facilitate introduction of the sheath into the uterine cavity. The single use sheath includes a working channel to permit the introduction of instrumentation. The reusable fiber optic hysteroscope is designed with optical lenses for visualization and optical fibers for illumination. The obturator is inserted into the working channel of the sheath and the hysteroscope is inserted into a designated lumen of the sheath. The Operative Hysteroscopy System can be combined with a hysteroscopic fluid management system (not the subject of this submission) to provide continuous flow hysteroscopy capability. The hysteroscope can be used with standard O.R. camera couplers.

5. Intended Use

Interlace Medical Operative Hysteroscopy System is used to provide viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

6. Comparison of Technological Characteristics

The Interlace Medical Operative Hysteroscopy System is substantially equivalent in design, materials, construction and intended use as that of the predicate. The principal of operation of both devices are exactly the same. Since the Interlace Medical Operative Hysteroscopy System has the same intended use and

technological characteristics as the predicate device, the Interlace Medical Operative Hysteroscopy System does not raise any new safety and efficacy concerns when compared to the similar legally marketed device.

The descriptive characteristics demonstrate that the Interlace Medical Operative Hysteroscopy System are substantially equivalent to the predicate device and is capable of safely and accurately performing the stated intended use.

7 Performance Testing
The Interlace Medical Operative Hysteroscopy System meets electrical safety standards.

8. Statement of Equivalency
The Interlace Medical Operative Hysteroscopy System is substantially equivalent in design, materials, construction and intended use as that of the predicate. The principal of operation of both devices are exactly the same. Since the Interlace Operative Hysteroscopy System has the same in intended use and technological characteristics as the predicate device, the Interlace Operative Hysteroscopy System does not raise any new safety and efficacy concerns when compared to the similar legally marketed device.

The descriptive characteristics demonstrate that the Interlace Operative Hysteroscopy System is substantially equivalent to the predicate device and is capable of safely and accurately performing the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 2008

Mr. Ron Adams
Chief Technical Officer
Interlace Medical
139 Newbury Street
FRAMINGHAM MA 01701

Re: K081070
Trade Name: Interlace Medical Operative Hysteroscopy System
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated: June 13, 2008
Received: June 17, 2008

Dear Mr. Adams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): TBD K081070

Device Name: Interlace Medical Operative Hysteroscopy System

Indications For Use:

Interlace Medical Operative Hysteroscopy System is used to provide viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K081070